

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BAUSCH & LOMB INCORPORATED &)
PF CONSUMER HEALTHCARE 1 LLC,)

Plaintiffs,)

v.)

SBH HOLDINGS LLC,)

Defendant.)

Civil Action No. 20-1463-GBW-CJB

REPORT AND RECOMMENDATION

In this patent action filed by Plaintiffs Bausch & Lomb Incorporated and PF Consumer Healthcare 1 LLC (“Plaintiffs”) against Defendant SBH Holdings LLC (“SBH” or “Defendant”), Plaintiffs allege infringement of United States Patent Nos. 6,660,297 (the “’297 patent”) and 8,603,522 (the “’522 patent” and collectively with the ’297 patent, “the asserted patents”). Presently pending before the Court is Defendant’s motion for summary judgment no. 3, by which Defendant moves for summary judgment on Plaintiffs’ claim of infringement based on the doctrine of equivalents (the “Motion”). (D.I. 178; *see also* D.I. 247 at 1) Plaintiffs oppose the Motion. For the reasons set forth below, the Court recommends that the Motion be DENIED.

I. BACKGROUND

Plaintiffs filed this action on October 28, 2020. (D.I. 1) This case has been referred to the Court by United States District Judge Gregory B. Williams to resolve all pre-trial matters up to and including summary judgment motions, pursuant to 28 U.S.C. § 636(b). (D.I. 40; D.I. 143)

Defendant filed the instant Motion on September 6, 2024. (D.I. 178) The Motion was fully briefed as of November 7, 2024. (D.I. 226) A trial is set to begin on April 21, 2025. (D.I. 241)

The Court here writes primarily for the parties, and so any facts relevant to this Report and Recommendation will be discussed in Section III below.

II. STANDARD OF REVIEW

Summary judgment is appropriate where “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585 n.10 (1986). If the moving party has sufficiently demonstrated the absence of such a dispute, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Id.* at 587 (internal quotation marks, citation and emphasis omitted). If the nonmoving party fails to make a sufficient showing in this regard, then the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, the Court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

However, in order to defeat a motion for summary judgment, the nonmoving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co.*, 475 U.S. at 586. The “mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). Facts that could alter the outcome are “material,” and a factual dispute is “genuine,” only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* at 248. “If the

evidence is merely colorable . . . or is not significantly probative . . . summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted).

A party asserting that a fact cannot be—or, alternatively, asserting that a fact is—genuinely disputed must support the assertion either by “citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials;” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B).

III. DISCUSSION

Plaintiffs assert that Defendant infringes claims 19, 24 and 31-32 of the '297 patent and claims 1, 4-6, 8, 11, 15-16 and 20 of the '522 patent (collectively, the “asserted claims”) by making and selling its MacularProtect® products (the “accused products”). (D.I. 166, ex. 4 at ¶¶ 44, 47, 50-51) As relevant to this Motion, the asserted claims of the '297 patent recite a composition that includes “approximately 7 to 10 times the RDA [recommended dietary allowance] of vitamin C” and the asserted claims of the '522 patent recite a method of administering a composition that includes “not less than approximately 420 mg and not more than approximately 600 mg vitamin C” or “approximately 7 to 10 times the RDA of vitamin C” (the “vitamin C limitation”). (*See, e.g.*, '297 patent, reexamination certificate at col. 2:7, 2:51; '522 patent, cols. 9:60-62, 10:43)¹ The Court construed “approximately” with respect to the

¹ The specification of the '297 patent teaches that the RDA of vitamin C is 60 mg, so 7 to 10 times the RDA of vitamin C is 420 mg to 600 mg of vitamin C. ('297 patent, col. 5:8-9; D.I. 166, ex. 4 at ¶ 62)

amount of vitamin C in the vitamin C limitation to mean “reasonably close to,” in accordance with the term’s plain and ordinary meaning. (D.I. 108 at 11-12; D.I. 189 at 6-7)

Defendant’s accused products contain 750 mg of vitamin C. (D.I. 166, ex. 4 at ¶ 50)

And so Plaintiffs are arguing here that the accused products infringe the vitamin C limitation not literally, but instead under the doctrine of equivalents (“DOE”). (*Id.* at ¶ 63) “Even when an accused product does not meet each and every claim element literally, it may nevertheless be found to infringe the claim if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.” *Intendis GmbH v. Glenmark Pharms. Inc., USA*, 822 F.3d 1355, 1360 (Fed. Cir. 2016) (certain internal quotation marks and citations omitted). The DOE is applied to individual elements of the claim, not to the invention as a whole. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997).²

Infringement under the DOE is a question of fact. *Intendis GmbH*, 822 F.3d at 1360.

With its Motion, Defendant responds by asserting that, as a matter of law, Plaintiffs cannot rely on the DOE to prove that Defendant’s accused products infringe the vitamin C limitation of the asserted claims. (D.I. 151 at 2, 7-10; D.I. 226 at 6-9) That is so, according to Defendant, because “Federal Circuit law has established that where a fuzzy claim term such as ‘approximately’ has been construed, whether with a wider numerical range or simply by words

² There are two frameworks for establishing equivalence: (1) the function-way-result (“FWR”) test; and (2) the “insubstantial differences” test. *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 866 (Fed. Cir. 2017). “To succeed on a [DOE] theory, the patentee must demonstrate equivalence under one of these two tests.” *Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1347 (Fed. Cir. 2013). The FWR test requires the patentee “to show, for each claim limitation, that the accused product ‘performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product.’” *Id.* (citation omitted). The insubstantial differences test asks whether the accused product or process is substantially different from what is patented. *Mylan Institutional LLC*, 857 F.3d at 866.

(as in this case), the broader limits described for *literal* interpretation are fixed and cannot be further expanded using the doctrine of equivalents.” (D.I. 151 at 2 (emphasis in original), 9-10)

For their part, Plaintiffs retort that Defendant has got the law wrong, and that the DOE remains available here. (D.I. 192 at 15) Plaintiffs assert that when a claim limitation includes a word like “approximately,” that does not automatically preclude reliance on the DOE; instead, use of such a term forecloses DOE application only if it has been construed to capture the equivalents to the claimed range within the literal scope of the claim. (*Id.* at 9-14) And here, Plaintiffs contend, the Court did not construe the term “approximately” in the vitamin C limitation to encompass equivalents within the literal scope of the claim term. (*Id.* at 14-15)

For the reasons set out below, the binding case law relevant to this issue better aligns with Plaintiffs’ position.

As an initial matter, Defendant’s position ignores the fact that the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have applied the DOE to a claim limitation that included the term “approximately.” (*See id.* at 9-10) In *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997), the Supreme Court considered whether the patentee could rely on the DOE to argue that the defendant’s accused process infringed the limitation “at a pH from *approximately* 6.0 to 9.0.” 520 U.S. at 22-23 (emphasis added). At trial in the district court, the jury had found that the defendant’s process, which involved a pH of 5.0, infringed under the DOE; the Federal Circuit later affirmed. *Id.* at 23. The Supreme Court found that the patentee could argue DOE with respect to this limitation (while also clarifying that prosecution history estoppel could serve as a bar to preclude infringement by equivalents if the applicant amended the element at issue for a reason relating to patentability). *Id.* at 32-34. Nowhere in its opinion did the Supreme Court say that DOE was unavailable to the patentee

because applying the DOE would allow the term “approximately 6.0” to encompass equivalents of equivalents. The Supreme Court remanded the case to the Federal Circuit to consider issues relating to prosecution history estoppel. *Id.* at 34; *see also, e.g., Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, C.A. No. 17-1612 (MN) (CJB), 2022 WL 2753636, at *2 (D. Del. June 30, 2022) (“The Supreme Court [in *Warner-Jenkinson*] did not hold that no equivalents exist as a matter of law and, in fact, remanded the case to the Federal Circuit with instructions to analyze infringement of [the ‘approximately 6.0’] limitation under the” DOE.).

On remand, the Federal Circuit reaffirmed its finding that there was substantial evidence to support the jury’s verdict that the accused product’s pH of 5.0 infringed the limitation requiring a pH of “approximately 6.0 to 9.0” under the DOE. *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 114 F.3d 1161, 1164 (Fed. Cir. 1997) (“Although there is nothing in the written description part of the specification to indicate that the invention extends beyond the specific range given in the claim, there is substantial record evidence to prove that one of ordinary skill in the art would know that performing ultrafiltration at a pH of 5.0 will allow the membrane to perform substantially the same function in substantially the same way to reach substantially the same result as performing ultrafiltration at 6.0.”).³ And again, there, the Federal Circuit never articulated that the DOE could not apply because the claim limitation at issue already included the term “approximately.”⁴

³ The Federal Circuit remanded the case to the district court, so that the district court could consider the issue of whether prosecution history estoppel barred application of the DOE—in light of the fact that the patentee had amended the claim to place a lower pH limit of “approximately 6.0” on the claimed process. *Warner-Jenkinson*, 114 F.3d at 1162-63.

⁴ Similarly, in *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211 (Fed. Cir. 1995), the Federal Circuit upheld the district court’s finding that accused products with a ratio of

Following *Warner-Jenkinson*, the Federal Circuit held that the DOE was available with respect to the claim term “between 10^{-6} and 10^{-4} $\mu\text{mol}/\text{mm}^3$ [.]” *U.S. Philips Corp. v. Iwasaki Elec. Co.*, 505 F.3d 1371, 1376, 1379 (Fed. Cir. 2007). In doing so, the Federal Circuit noted that “the phrase is also essentially the same as that used in *Warner-Jenkinson*, with the exception of the absence of the qualifier ‘approximately’”—but that “terms like ‘approximately’ serve only to expand the scope of literal infringement, not to enable application of the doctrine of equivalents.” *Id.* at 1379. To that end, the Federal Circuit observed that “[n]otably, the Supreme Court in *Warner-Jenkinson* did not even mention the qualifier in allowing consideration of the doctrine of equivalents.” *Id.*; see also *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1293 (Fed. Cir. 2010) (“The fact that the claim does not contain words of approximation (i.e., ‘about at least 3500 hr*ng/mL’) does not affect the analysis [of whether the DOE was available to the patentee, since such terms] serve only to expand the scope of literal infringement, not to enable the application of the [DOE.] The proper inquiry is whether the accused value is insubstantially different from the claimed value.”).

In light of this, how does Defendant argue that if a claim term like “approximately” has been construed “to a somewhat broader range, whether numerically or simply by words, the plaintiff cannot use” the DOE to assert infringement of that claim term? (D.I. 151 at 9-10) To do so, Defendant relies primarily upon the Federal Circuit’s decision in *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351 (Fed. Cir. 2008).

In *Cohesive*, the Federal Circuit concluded that the patentee could not rely on the DOE to assert that the accused product infringed a claim limitation requiring that column particles have

methylenes to amide groups of 4:1 infringed a claim limitation requiring a ratio of methylenes to amide groups “within the range of about 5:1 to about 7:1” under the DOE. 66 F.3d at 1217-20.

average diameters “greater than about 30 μm .” 543 F.3d at 1367, 1372. The Federal Circuit explained that the district court had erred in construing “greater than about 30 μm ” expressly to exclude the claimed device, and thereafter engaged in a claim construction analysis for the limitation at issue—including as to the meaning of the word “about”—using what it called a “functional approach.” *Id.* at 1367-70. In doing so, the Court focused on the “criticality” of the numerical limitation to the invention—i.e., it examined what purpose the numerical limitation served, in order to determine how much smaller the diameter could be and still serve that purpose. *Id.* at 1368 (citation omitted). The Court looked to some examples in the patent that made it clear why the claims placed a low-end limit on particle size; it further noted that because the particles at issue were non-spherical, not uniformly shaped and not measurable to a precise degree, it was unsurprising that the patentee would claim “about 30 μm ” instead of precisely “30 μm .” *Id.* at 1369 (internal quotation marks and citation omitted). The Court additionally considered statements in the specification that bore on the range that “about” was intended to capture in the context of the invention. *Id.* Based on this intrinsic evidence, the Federal Circuit held that the construction of “greater than about 30 μm ” is “either (1) greater than 25.434 μm , or (2) *both* greater than 23.044 μm *and* of sufficiently large size to assure that the column is capable of attaining turbulence.” *Id.* at 1369-71 (emphasis in original).

In light of that construction, the Federal Circuit held that the DOE was not available to the patentee. *Id.* at 1371-72. It observed that its construction of “about 30 μm ” was coextensive with a DOE analysis, explaining that the term “encompasses particle diameters that perform the same function, in the same way, with the same result as the 30 μm particles[.]” *Id.* at 1372. And because of these circumstances—i.e., where “the ‘about 30 μm ’ limitation [therefore] already literally encompasses diameters that are equivalent to 30 μm in the context of the patent” such

that “any particle diameter that performs the same function, in the same way, with the same result as a 30 μm diameter is already within the literal scope of the claim”—the patentee “cannot rely on the doctrine of equivalents to encompass equivalents of equivalents.” *Id.* at 1372 (“Where, as here, a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim, the doctrine of equivalents is unavailable to further broaden the scope of the claim.”).

According to Defendant, *Cohesive* stands for the proposition that if a claim term contains a term of approximation (e.g., “about” or “approximately”) and that claim term is given a non-quantitative construction (such as “reasonably close to[,]” as is the case here), the plaintiff cannot rely on the DOE to argue infringement with respect to that claim limitation as a matter of law—because that construction is bringing what would otherwise be equivalents of a limitation into the literal scope of the claim. (D.I. 151 at 9-10; D.I. 226 at 8-9) The Court acknowledges that *Cohesive* is a difficult decision to parse. But in the Court’s view, Defendant’s reading of *Cohesive* is incorrect. The Court so concludes for at least the following three reasons.

First, and most importantly, there is one Federal Circuit opinion that provides the greatest amount of guidance as to how *Cohesive*’s analysis of this DOE issue should be interpreted—*Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151 (Fed. Cir. 2012)—and *Pozen* supports Plaintiffs’ view. (See D.I. 192 at 12) In *Pozen*, one of the asserted claims required “substantially all of said triptan is in the first layer of said tablet and substantially all of said naproxen is in a second, separate layer” (the “substantially all term”). 696 F.3d at 1169 (internal quotation marks and citation omitted). The district court had construed the substantially all term to mean “at least 90%, and preferably greater than 95%, of the total triptan present in the tablet is included within one distinct layer and at least 90%, and preferably greater than 95%, of the naproxen present in

the tablet is included within a second distinct layer.” *Id.* (internal quotation marks and citation omitted). As relevant here, one defendant’s accused products contained 85% of the naproxen in the second layer, and the other defendant’s accused product contained 85% of the total triptan in the product in one layer. *Id.* Literal infringement was not at issue, and so the infringement question, then, was whether, under the DOE, a layer with 85% of the agent is equivalent to one with 90% of the agent. *Id.* at 1167, 1170-71.

The district court found that the defendants’ products infringed the substantially all term of the asserted claim under the DOE. *Id.* at 1168, 1171. While recognizing that its claim construction set forth specific percentages, the district court explained that “absent more limiting language in the intrinsic record[,] the doctrine of equivalents can be applied to find infringement where the accused value is insubstantially different from the claimed value.” *Id.* at 1169 (internal quotation marks and citation omitted). On appeal, defendants argued that “substantially all” is a “fuzzy” quantitative limitation not entitled to equivalents; according to defendants, the term “substantially” was used to capture values lower than 100% (with the district court construing the term to include amounts as low as 90%), and so the patentee should not be able to go below that 90% floor to encompass “equivalents of equivalents.” *Id.* at 1170 (internal quotation marks and citation omitted).

The *Pozen* Court began its analysis by reiterating *Cohesive*’s holding that where “a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim, the doctrine of equivalents is unavailable to further broaden the scope of the claim.” *Id.* (quoting *Cohesive*, 543 F.3d at 1372). But it did *not* then proceed on to apply *Cohesive*’s holding to the facts before it. Instead, the *Pozen* Court further explained that while the substantially all term “itself is a qualitative measure, the claim construction pulls directly from

the specification to give the [substantially all term] a quantitative definition, specifically, ‘at least 90%, and preferably greater than 95%[.]’” *Id.* (internal citation omitted). The *Pozen* Court next emphasized that the DOE is not “foreclosed with respect to claimed ranges[.]” *Id.* Finally, the Federal Circuit held that the DOE was available for the substantially all term *because the patentee “never stated that ‘at least 90%, and preferably greater than 95%’ should be an absolute floor.”* *Id.* (emphasis added). In other words, while the *literal scope* of the substantially all term thus meant, as relevant here, “at least 90%, and preferably greater than 95%,” equivalents of that literal scope were still available to the patentee—because the patent’s language had not brought what would otherwise be equivalents of the limitation into the literal scope of the claim. Thus, the *Pozen* Court ultimately concluded that, under the DOE, a tablet layer with 85% of the agent could “fairly be characterized as an insubstantial change from a tablet layer with 90% of the agent.” *Id.* at 1170-71.

Importantly, in support of this conclusion, the *Pozen* Court analogized the facts before it to those in *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F.3d 1339 (Fed. Cir. 2006). 696 F.3d at 1170. In *Kemin*, the patentee had challenged the jury’s verdict of, *inter alia*, noninfringement under the DOE. The relevant claim term included language of approximation—“substantially free from other carotenoids”—that, based on a statement in the specification, had been construed to mean “*significantly less than 10% of other carotenoids[.]*” 464 F.3d at 1349 (emphasis added). Notably, then, in *Kemin*, the construction of the “substantially free” term itself contained a term of approximation (“significantly less than”). Nevertheless, the *Kemin* Court noted that because “*Kemin has not argued that the phrase ‘significantly less than 10%’ has a precise upper limit[.]*” a reasonable jury could determine that the percentage of “other carotenoids” in the defendant’s products (which ranged from 6.14 to

9.86) might or might not either: (1) literally infringe the “significantly less than” limitation; or (2) meet that limitation pursuant to the DOE. *Id.* In other words, the *Kemin* Court held that the DOE was available to the patentee, even though the claim construction for the term at issue included language of approximation. *Id.* (emphasis added). Similar to *Pozen*, the DOE was available in *Kemin* because the “substantially free from other carotenoids” term had not been construed in such a way as to bring what otherwise would be equivalents into the literal scope of the claim.

In the Court’s view, cases like *Pozen* and *Kemin* indicate that even if a claim term contains a term of approximation, and even if the construction of that claim term contains further language of approximation, a patentee is not necessarily foreclosed from relying on the DOE as a matter of law—so long as the term has not already been construed to capture all possible equivalents (and absolutely exclude any other possibilities). (See D.I. 192 at 13-14) If the claim term at issue or its construction cannot be said to set an absolute and final upper limit or floor on what the claim can reach, then the patentee can assert DOE with respect to that limitation. Relatedly, in *Cohesive*, it appears that it was the claim construction for the “about” term—one that, according to the *Cohesive* Court, explicitly encapsulated all functional equivalents—that was the key to the Court’s holding. 543 F.3d at 1372 (“As our construction makes clear, ‘about 30 μm ’ encompasses particle diameters that *perform the same function, in the same way, with the same result* as the 30 μm particles, as long as those diameters are within the range left open by the specific disclosures of the specification.”) (emphasis added); see also *Tris Pharma, Inc. v. Teva Pharms. USA, Inc.*, Civ. No. 20-05212 (KM)(ESK), 2022 WL 4082190, at *29 (D.N.J. Sept. 6, 2022) (rejecting the position that “*Cohesive* holds that the word ‘about’ limits the use of the doctrine of equivalents” in all circumstances; rather, in the unique circumstances of that case,

“the Federal Circuit construed ‘about,’ in the absence of a more specific definition, as capturing all equivalents”); *Bayer Healthcare Pharms., Inc. v. River’s Edge Pharms., LLC*, CIVIL ACTION NO. 1:11-CV-1634-LMM, 2015 WL 11143147, at *6 (N.D. Ga. Nov. 13, 2015) (“Essentially, then, the *Cohesive* court carried out a doctrine of equivalents analysis at claim construction when it sought to determine what particle sizes would perform the same way to obtain the intended result” and thus “[i]t did not need to conduct the analysis again at the infringement stage because the construction already included all equivalents because of the way the *Cohesive* court determined criticality during claim construction.”).⁵

Second, the Court’s conclusion here gibes with a typical understanding of how the claim construction and literal/DOE infringement inquiries are supposed to work. First, a court construes a claim term, in order to determine its literal scope. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). Here, as construed, the literal scope of the vitamin C limitation is “reasonably close to 7 to 10 times the RDA of vitamin C” for the asserted

⁵ The other Federal Circuit case that Defendant relies upon for its assertion that a patentee cannot utilize the DOE to assert infringement of limitations that include “approximately,” *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Lab’ys, Ltd.*, 476 F.3d 1321 (Fed. Cir. 2007), (D.I. 151 at 9), also involved facts unique to that case. There, the Federal Circuit found that the district court had properly granted summary judgment of non-infringement under the DOE with respect to a claim term reciting an “about 1:5” ratio and an accused formulation that had a ratio of 1:8.67. 476 F.3d at 1325, 1329. In doing so, the Court examined the criticality of the 1:5 ratio to the claim by noting that the 1:5 ratio, along with a 1:1 ratio, was distinctly claimed and distinguished from other broader claims to ranges of weight ratios; this indicated that the inventors “intended a range when they claimed one and something more precise when they did not.” *Id.* at 1327. Additional statements in the specification further supported that the ratio of 1:5 was “meant to encompass compositions very close to that ratio.” *Id.* The *Ortho-McNeil* Court agreed with the lower court’s construction of “about 1:5” to mean “approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1.” *Id.* at 1328. Based on statements in the specification and the prosecution history, the Court explained that the criticality of the “about 1:5” ratio “necessitates a narrow claim construction and range of equivalents that does not encompass” the defendant’s product. *Id.* at 1328-29.

claims of the '297 patent and certain asserted claims of the '522 patent, and “reasonably close to 420 mg and not more than reasonably close to 600 mg vitamin C” for the remaining asserted claims of the '522 patent. The literal infringement analysis, then, would then be about assessing whether the accused product includes an amount of vitamin C that is reasonably close to 7 to 10 times the RDA of vitamin C or is reasonably close to 420 mg and not more than reasonably close to 600 mg vitamin C. *See U.S. Philips Corp. v. Iwasaki Elec. Co.*, 505 F.3d 1371, 1379 (Fed. Cir. 2007) (“However, terms like ‘approximately’ serve only to expand the scope of literal infringement, not to enable application of the doctrine of equivalents.”); *see also Markman*, 52 F.3d at 976. Expert testimony would no doubt be employed to assess whether that was so (and perhaps also to help understand what amount of vitamin C would be *outside* the boundaries of literal infringement). *See Par Pharm., Inc. v. Hospira, Inc.*, 835 F. App’x 578, 584 (Fed. Cir. 2020) (“Although defining the outer reaches of ‘about’ in a claimed range can be a matter of claim construction, [w]hen the claims are applied to an accused device, it is a question of technologic fact whether the accused device meets a reasonable meaning of ‘about’ in the particular circumstances.”) (internal quotation marks and citation omitted). Say that the outcome of the factfinder’s analysis was that the accused product does *not* literally infringe the vitamin C limitation. Then the factfinder would turn to a DOE analysis—no doubt again aided by reliance on expert testimony. And that DOE inquiry would involve assessing whether there is equivalence between the amount of vitamin C in the accused products and the amount of vitamin C that is permitted by the asserted claims’ vitamin C limitation. To be sure, this inquiry might be made somewhat more difficult because the construction of the vitamin C limitation includes a term of degree. But there is no reason why it could not occur—just like it does in nearly all other patent cases in which a plaintiff seeks to pursue infringement claims as to both literal

infringement and infringement under the DOE. *See Pozen*, 696 F.3d at 1167; *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1218 (Fed. Cir. 1995) (“When literal infringement is not established, infringement may be proved under the doctrine of equivalents when there is not a substantial difference between the claimed invention and the accused product.”). The Court is unpersuaded that any kind of different process should happen here, just because the vitamin C claim term uses the word “approximately” (which has been construed to mean “reasonably close to”). *See, e.g., Chemours*, 2022 WL 2753636, at *2 (noting that the “Federal Circuit in *Cohesive* did not announce a bright-line legal test” with respect to claim limitations reciting “about”).⁶

Third, since *Cohesive* issued, a number of other courts have rejected the notion that a patentee can never rely on the DOE to assert infringement of a claim term reciting “about”—even where that term was, in turn, construed in a manner including a term of degree. Indeed, other judges of this Court have reached just this conclusion. *See, e.g., Chemours*, 2022 WL 2753636, at *2 (rejecting the defendant’s argument that the DOE is unavailable as a matter of law with respect to a claim term requiring a melt flow rate of “about 30±3 g/10 min”);⁷ *see also*,

⁶ In its briefing, Defendant makes an interesting rhetorical point when it argues that: (1) since, for example, the literal scope of one part of one claim term at issue requires that the amount of vitamin C be “*reasonably* close to 600 mg”; then (2) this would mean that an amount of vitamin C said to be equivalent to the claim limitation must by definition *not be* “*reasonably* close to 600 mg”; and so (3) it seems strange to conclude that such an amount—i.e., an amount that is *not reasonably* close to 600 mg—could be said to infringe a claim under the DOE. (D.I. 226 at 8 (emphasis added)) After all, the DOE is meant to allow the patentee to “claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through *trivial* changes.” *Pozen*, 696 F.3d at 1167 (internal quotation marks and citation omitted) (emphasis added). That type of linguistic argument might well be an effective part of Defendant’s trial presentation as to why Plaintiffs’ DOE position should not prevail *on the merits*. But the Court does not see why it suggests that there should *never be a merits argument* put before the factfinder all at.

⁷ In *Chemours*, “about” was construed to mean “approximately.” *Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, Civil Action No. 17-1612-MN-CJB, 2022 WL 605357, at *9 (D.

e.g., Par Pharm., Inc. v. Hospira, Inc., 420 F. Supp. 3d 256, 278 (D. Del. 2019) (finding that “[t]o the extent that Hospira’s ANDA Product does not literally meet the claim limitations ‘about 6 to 8 mg/mL of a tonicity regulating agent’ or ‘about 2.8 to 3.8 mg/mL of a pH raising agent,’ Hospira’s ANDA Product meets those claim limitations under” the DOE),⁸ *aff’d*, 835 F. App’x 578 (Fed. Cir. 2020). Other district courts have followed suit. *Tris Pharma, Inc.*, 2022 WL 4082190, at *29 (finding that *Cohesive* did not establish a bright line rule that the DOE does not apply to claim terms including “about,” and explaining that in the asserted patent at issue, “‘about’ specifically means +/- 10%, and that definition might or might not extend to the limit of the doctrine of equivalents”); *Procter & Gamble Co. v. Team Techs., Inc.*, Case No. 1:12-cv-552, 2014 WL 12531486, at *13 (S.D. Ohio July 3, 2014) (holding that even if the accused products did not fall within the literal scope of the claim term “less than about 5,” they would infringe this limitation under the DOE where, “for all the reasons that the literal scope of the term ‘less than about 5’ is entitled to a broad construction, the range of applicable equivalents is also broad”).⁹

Del. Jan. 13, 2022), *report and recommendation adopted*, 2022 WL 855518 (D. Del. Mar. 23, 2022).

⁸ In this case too, the word “about” was construed to mean “approximate.” *Par Pharm.*, 420 F. Supp. 3d at 263.

⁹ That said, the Court also recognizes that some non-binding opinions from other district courts do seem to hold that *Cohesive* established a bright-line rule that a patentee cannot, as a matter of law, rely on the DOE to assert infringement of a limitation that includes a term like “about” (or at least cannot do so in circumstances where the term of approximation is construed to have an equally non-quantitative definition), because the limitation would already encompass equivalents as part of the claim’s literal scope. *See Takeda Pharm. Co. v. TWI Pharms., Inc.*, 87 F. Supp. 3d 1263, 1281-82 (N.D. Cal. 2015) (holding that where the court had construed “about” to mean “approximately,” rather than a specific numerical range, it had “already concluded that the claim’s literal scope necessarily includes equivalents” and that because “equivalents are already encompassed by the claim’s literal scope,” the DOE was not available to the patentee as a matter of law) (citing *Cohesive*); *see also Regents of Univ. of Minn. v. AGA Med. Corp.*, No. 07-CV-4732 (PJS/LIB), 2011 WL 13943, at *13 (D. Minn. Jan. 4, 2011) (concluding that “when

Turning again to the facts before the Court here, they are different than those at play in *Cohesive*. Here, unlike in *Cohesive*, the Court did not conduct any type of DOE analysis (using either the FWR test or the insubstantial differences test, or otherwise) when it construed the vitamin C limitation. Nor did the Court hold that the patent otherwise states that the vitamin C limitation cannot encompass any equivalents outside of the term's literal scope. Thus, in this case, the Court's claim construction of the term "approximately" to mean "reasonably close to" is not an automatic bar to the application of the DOE. Instead, Plaintiffs should be permitted to present their evidence to the jury regarding whether the accused products infringe the vitamin C limitation under the DOE.

IV. CONCLUSION

For the foregoing reasons, the Court recommends that the Motion be DENIED.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. Any objections to this Report and Recommendation should be filed by **March 26, 2025**; any responses should be filed by **April 4, 2025**. The failure

a numerical limitation is fuzzy to begin with, to allow the patentee to reach numbers outside the already-expanded range captured by the literal claim language is to say, in effect, that the fuzzy limitation is irrelevant" and that under *Cohesive*, "the [DOE] is not available to expand the scope of the already-fuzzy ratio limitations beyond their literal reach"); *Flexsys Am. LP v. Kumho Tire U.S.A., Inc.*, 726 F. Supp. 2d 778, 794 (N.D. Ohio 2010) ("The doctrine of equivalents is simply not available to Flexsys in the present case to extend the 4.7% upper limit of the 'about 4%' claim language to encompass 5.24%" because "[b]y using the term 'about' . . . Flexsys has already defined the outer range for covered protic material percentages at under 4.7%" and "[t]he doctrine of equivalents cannot be utilized to extend that range any further."); *see also Tolmar Therapeutics, Inc. v. Foresee Pharms. Co.*, No. 21cv15782 (EP) (CLW), 2022 WL 13858026, at *4-5 (D.N.J. Oct. 24, 2022).

But for the reasons discussed above, the Court respectfully disagrees with these opinions, as the Federal Circuit's caselaw does not indicate that any such bright-line rule has been established.

of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the District Court's website, located at <http://www.ded.uscourts.gov>.

Dated: March 17, 2025



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE